

Use of structured self-monitoring of blood glucose improves HbA1c and diabetes-related distress in Australian adults with non-insulin-treated type 2 diabetes: first results from 'STeP IT UP'

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BACKGROUND

- Structured self-monitoring of blood glucose (SMBG) is an approach in which blood glucose data are gathered according to a defined regimen, interpreted and utilised to make appropriate pharmacologic and/or lifestyle adjustments.^{1,2}
- Clinical studies have shown that use of structured SMBG:
 - improves glycaemic control³⁻⁵
 - facilitates more frequent, aggressive therapy intensification⁶
 - reduces depression and diabetes-related distress⁷
 - reduces cardiovascular risk^{8,9}
 - enhances patient understanding and engagement¹⁰
 - improves treatment satisfaction and quality of life^{10,11}
 - is cost-effective^{3,12}
- Observational studies have demonstrated that use of structured SMBG is both practical and sustainable in real world clinical settings.^{13,14}
- Although the benefits of structured SMBG have been demonstrated in several US and European studies, the generalisability of these findings have not yet been shown in Australia.

AIMS

- The aims of the Structured Testing Program Implementation Trial (STeP IT UP) were: to assess the feasibility of implementing the original STeP study protocol in the real world.
- To observe the impact of structured SMBG on HbA1c and diabetes-related distress in adults with non-insulin-treated type 2 diabetes managed in primary care settings across Australia.

METHODS

- This was a 24-week, multi-centre, uncontrolled, observational study.
- 98 adults with non-insulin-treated type 2 diabetes managed in primary care settings across Australia are included in this analysis (Table 1).
- Australian clinicians with structured SMBG experience trained participants to use and interpret structured SMBG (3-day, 7-point profiles), using the Accu-Chek 360 View tool.³ Using this paper tool, adults with type 2 diabetes record a 7-point SMBG profile (fasting, preprandial/ 2-h postprandial at each meal, bedtime), document meal sizes and energy levels and comment on their SMBG experiences.
- Participants completed the tool prior to their visits at weeks 4, 12 and 24; results were discussed at each visit.
- Assessments of HbA1c levels and blood glucose values were made at weeks 4, 12 and 24.
- Blood glucose values were categorised as:
 - Low: <4 mmol/L
 - Within Target: 4-10 mmol/L
 - High: >10 mmol/L

Measurements of diabetes-related distress were taken at baseline and week 24.

- Data at weeks 12 and 24 (last non-baseline value carried forward); data regarding change in HbA1c were available for 98 participants.

Table 1. Participant characteristics at baseline (N=98)

Characteristic	Mean (SD) or N (%)
Age, years	61.9 (11.8)
Gender, female	37 (37.8)
HbA1c, %	8.62 (1.07)
BMI, kg/m ²	31.7 (6.3)
Weight, kg	90.6 (19.0)

SD = standard deviation

REFERENCES

- Parkin CG, Buskirk A, Hinnen DA, Axel-Schweitzer M. Results that matter: Structured vs. unstructured self-monitoring of blood glucose in type 2 diabetes. *Diabetes Res Clin Pract* 2012.
- International Diabetes Federation. Global guideline on self-monitoring of blood glucose in non-insulin treated type 2 diabetes. 2009 (www.idf.org)
- Polonsky WH, Fisher L, Schikman CH, et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study. *Diabetes Care* 2011;34:262-7.
- Kempf K, Kruse J, Martin S. ROSSO-in-Praxis: a self-monitoring of blood glucose-structured 12-week lifestyle intervention significantly improves glucometabolic control of patients with type 2 diabetes mellitus. *Diabetes Technol Ther* 2010;12:547-53.
- Kato N, Cui J, M K. Structured self-monitoring of blood glucose reduces glycated hemoglobin in insulin-treated diabetes. *Journal of Diabetes Investigation* 2013;4:450-3.
- Polonsky W, Fisher L, Schikman C, et al. A structured self-monitoring of blood glucose approach in type 2 diabetes encourages more frequent, intensive, and effective physician interventions: results from the STeP study. *Diabetes Technol Ther* 2011;13:797-802.
- Fisher L, Parkin CG, Jelsovsy Z, et al. The impact of blood glucose monitoring on depression and distress in insulin-naïve patients with type 2 diabetes. *Current Medical Research and Opinion* 2011;27:39-46.
- Schnell O, Amann-Zalan I, Jelsovsy Z, et al. Changes in A1C levels are significantly associated with changes in levels of the cardiovascular risk biomarker hs-CRP: results from the SteP study. *Diabetes Care* 2013;36:2084-9.
- Mohan V, Ravikumar R, Poongothai S, et al. A single-center, open, comparative study of the effect of using self-monitoring of blood glucose to guide therapy on preclinical atherosclerotic markers in type 2 diabetic subjects. *J Diabetes Sci Technol* 2010;4:942-8.
- Kempf K, Kruse J, Martin S. ROSSO-in-Praxis Follow-Up: Long-Term Effects of Self-Monitoring of Blood Glucose on Weight, Hemoglobin A1c, and Quality of Life in Patients with Type 2 Diabetes Mellitus. *Diabetes Technol Ther* 2012;14:59-64.
- Fisher L, Polonsky WH, Parkin CG, et al. The impact of structured blood glucose testing on attitudes toward self-management among poorly controlled, insulin-naïve patients with type 2 diabetes. *Diabetes Res Clin Pract* 2012;96:149-55.
- Mast O, Polonsky WH, Fisher L, et al. Structured blood glucose monitoring reduces HbA1c levels and annual test strip consumption in poorly controlled, non-insulin treated type 2 diabetes: Results from the STeP Study. *Diabetologia* 2011;53(suppl1):S423-S4.
- Lalic N, Tankova T, Nourredine M, et al. Value and utility of structured self-monitoring of blood glucose in real world clinical practice: findings from a multinational observational study. *Diabetes Technol Ther* 2012;14:338-43.
- Friedman K, Noyes J, Parkin CG. 2-Year follow-up to STeP trial shows sustainability of structured self-monitoring of blood glucose utilization: results from the STeP practice logistics and usability survey (STeP PLUS). *Clinical Diabetes* 2013;15:344-7.

RESULTS

- Significant reductions in HbA1c from week 4 were seen at weeks 12 and 24 (Figure 1).
- No increases in hypoglycaemia (<4 mmol/L) were seen (Figure 2).
- Significant reductions in the percentage of high blood glucose values (>180 mg/dL / >10 mmol/L) were seen at weeks 12 and 24 (Figure 3).
- Significant increases in the percentage of blood glucose values within target range (4-10 mmol/L) were seen at weeks 12 and 24 (Figure 4).
- Diabetes-related distress decreased slightly from baseline (2.09 [1.01]) to week 12 (1.75[0.74], Δ -0.16[0.74], $p=0.061$) and reached significance by week 24 (1.69[0.83], Δ -0.22[0.83], $p=0.023$).

Figure 1. Change in HbA1c from baseline to Weeks 12 and 24

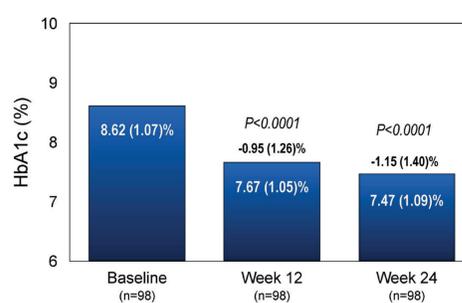


Figure 2. Change in Percentage of Low Blood Glucose Values (<4 mmol/L) from baseline to Weeks 12 and 24 (Profile Days)

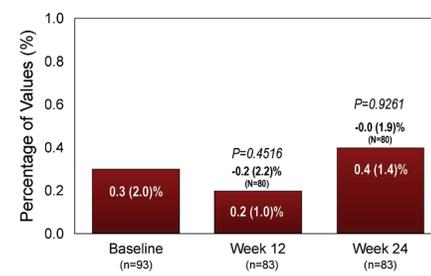


Figure 3. Change in Percentage of High Blood Glucose Values (>10 mmol/L) from baseline to Weeks 12 and 24 (Profile Days)

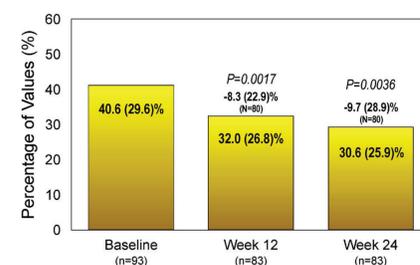
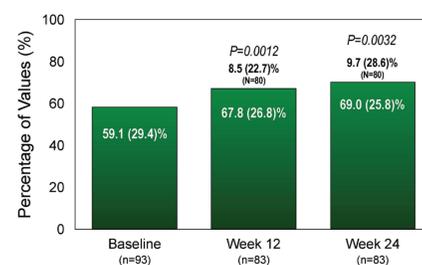


Figure 4. Change in Percentage of Blood Glucose Values Within Target Range (4-10 mmol/L) from baseline to Weeks 12 and 24 (Profile Days)



CONCLUSIONS

- We confirmed the transferability of the STeP Study protocol to real life primary care practice in Australia.
- In this analysis of an observational study, use of structured SMBG by Australian adults with non-insulin-treated type 2 diabetes, supported by primary care clinicians, is associated with significant improvements in glycaemic control without increasing hypoglycaemia.
- Over time, it appears that diabetes-related distress also decreases significantly.
- These findings support evidence already gathered from US and European studies, indicating that structured SMBG can improve both biomedical and psychological outcomes for adults with non-insulin-treated type 2 diabetes.

Enquiries

For further information, contact Prof Jane Speight (E: jspeight@acbrd.org.au). The Accu-Chek 360 View tool is available from: www.accu-chek.com.au.

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